

Application Serial No.: 10/748,484
Amendment dated: June 1, 2006
Response to Final Office Action dated April 5, 2006

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REMARKS

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1 and 2 are now in the case. Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

THE §101/§112, FIRST PARAGRAPH REJECTIONS

The Examiner has rejected claims 1 and 2 under 35 U.S.C. §101, alleging that the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Applicants traverse. The present invention is based on the discovery of a novel class II cytokine, which Applicants designated Zcyto10 (also known as IL-20). Specifically, Zcyto10 is described as a four-helix-bundle cytokines such as those found within the interferon/IL-10 class:

It is believed that Zcyto10 is of a member of the IL-10 subfamily of cytokines. Other members of this group include MDA-7, IL-19, and KFF.

Id at pg. 9, lines 4-5. Concurrent with the discovery of Zcyto10, Applicants identified ZcytoR7 (IL-20RA) as a novel cytokine receptor: "ZcytoR7, like all known class II receptors except for interferon-alpha/beta receptor alpha chain, has only a single class II CRM in its extracellular domain. ZcytoR7 appears to be a receptor for a helical cytokine of the interferon/IL-10 class." *See e.g.* US Patent No. 5,945,511. As stated in the present Application, it was subsequently confirmed that Zcyto10 bound to a receptor complex comprising ZcytoR7. *See e.g.*, Blumberg et al., Cell, 104:9-19, (2001) (copy enclosed).

Moreover, Applicants were the first to discover IL-20's biological function and its role in skin disorders. As stated in the present Application, IL-20 has been recognized to be involved with skin disorders: "Zcyto10 polypeptides can also be used to treat a number of skin conditions..., for example eczema, psoriasis or dry skin conditions in general or as related skin attentions." *See e.g.*, Specification at pg. 31, line

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35 through pg. 36, line 3; *see also*, Blumberg *et al.* To support this utility, Applicants describe the phenotypic effect that IL-20 transgenic mice present in Example 5. Specifically, these transgenic mice exhibit skin that was "tight and wrinkled" while the "skin of the zcyto10 expressing pups, *particularly those mice which had a high expression level of Zcyto10 tended to be thicker than the non-expressing pups.*" *Id* at pg. 39. Applicants strongly assert that the present Application has clearly demonstrated that IL-20 has a biological role or function in skin conditions such as psoriasis. As such, antagonists of IL-20, such as the presently claimed antibodies, would have an immediate therapeutic benefit or utility in the treatment of skin conditions such as psoriasis

Applicants have also enclosed a number of additional references that also support the asserted and specific utility that is clearly stated in the present Application. Rich and Kupper, Current Biology, 11:R531-R534 (2001) (copy enclosed), citing Applicants transgenic data summarized above, state that "Biological studies of IL-20 revealed that it has an important role in promoting hyperproliferation of keratinocytes and thereby modulating inflammation in the skin." Another reference, Volk *et al.*, TRENDS in Immunology, 22(8):414-417 (2001) (copy enclosed), also citing Applicants transgenic data, state that IL-20's "selective pro-inflammatory activities make [it] interesting new candidates for research and drug development." Rich, B. E., Expert Opin. Ther. Targets, 7(2):163-174 (2003) (copy enclosed) states that "IL-20 signaling appears to be a prominent component of cutaneous inflammation." Rich goes on to state that "The apparently specialized role of IL-20 signaling in cutaneous tissue may present an opportunity to create pharmaceutical interventions that selectively mitigate inflammatory processes in the skin while sparing inflammation in other tissues." *Id.* Thus, as clearly stated in the present Application, IL-20 antagonists, such as the antibodies as claimed, would be useful in generating therapeutics for treating such skin conditions.

Accordingly, Applicants assert that Zcyto10, and thus antibodies that bind to Zcyto10, have a recognizable biological function and therapeutic benefit which would be understood and appreciated by one skilled in the art upon reading the present Application. Thus, the presently claimed Zcyto10 antibodies have a specific and substantial asserted utility which provide immediate benefit to the public. That is all that is required under 35 U.S.C. §101. Accordingly, Applicants respectfully request

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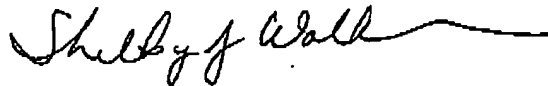
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consideration and withdrawal of the present rejections under 35 U.S.C. §101 and §112, first paragraph.

CONCLUSION

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

Respectfully Submitted,



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Enclosures:

Blumberg *et al.*, Cell, 104:9-19, (2001)
Rich and Kupper, Current Biology, 11:R531-R534 (2001)
Volk *et al.*, TRENDS in Immunology, 22(8):414-417 (2001)
Rich, B. E., Expert Opin. Ther. Targets, 7(2):165-174 (2003)

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